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GUIDANCE DOCUMENT 04-01
10 FEBURARY 2004

Electromagnetic Compatibility (EMC) Policy

1. Introduction. This instruction provides the necessary guidance to enable biomedical equipment technicians (BMETs) to manage the Electromagnetic Compatibility program for the Air Force Medical Service (AFMS). This guidance outlines the responsibilities for end users, local BMETs, and Medical Logistics.

2. Background.

2.1 Because of its concern for the public health and safety, the Center for Devices and Radiological Health (CDRH) part of the Food and Drug Administration (FDA), has been in the forefront of examining medical device Electromagnetic Interference (EMI) and recommending possible solutions. Extensive laboratory testing by CDRH, and others, has revealed that many devices can be susceptible to problems caused by EMI. In fact, the CDRH has been investigating incidents of device EMI, and working on solutions (e.g. the 1979 draft EMC standard for medical devices) since the late 1960's, when there was concern for EMI with cardiac pacemakers.

2.2 The key to addressing EMI is the education and recognition that EMI involves not only the device itself but also the environment in which it is used, and anything that may come into that environment. More than anything else, the concern with EMI must be viewed as a systems problem requiring a systems approach. In this case, the solution requires the involvement of the device industry, the EM source industry (e.g., power industry, telecommunications industry), the engineering community, the clinical users, the medical equipment and system maintainers, and the patients. The public must also play a part in the overall approach to recognizing and dealing with EMI.

2.3 Effective June 2000, the 608 to 614 MHz, 1395 to 1400 MHz, and 1429 to 1432 MHz spectrum was set aside for primary or co-primary use by eligible wireless medical telemetry users. The Federal Communications Commission (FCC) designated these spectrum bands for Wireless Medical Telemetry Service (WMTS) in the United States. It is possible that legacy telemetry devices/systems do reside in the unlicensed spectrum (2.4 GHz – 5 GHz). As legacy telemetry systems are upgraded/replaced, systems or devices operating in the WMTS spectrum shall be implemented.

3. Purpose.

3.1 To promote medical device Electromagnetic Compatibility (EMC) and minimize the risk of potential performance degradation of electronic medical devices resulting from EMI. The scope of this document is on equipment and devices within the environment of care that use radio frequency in their use and operation.

3.2 Identify devices and equipment that can be affected by EMI. The potential devices and equipment that could be affected include, but are not limited to:

3.2.1 Cellular/Personal Communication Service (PCS) Telephones

3.2.2. Two-Way Communication Devices (e.g. Walk-Abouts, Push-to-Talk)

3.2.3 Land Mobile Radio (LMR)

3.2.4 Wireless Local Area Networks (WLANs) and Components

3.2.5 Radio Frequency Identification (RFID) Systems

3.2.6 Portable Data Terminals (PDT) and Bar Code Scanners

3.2.7 Medical Telemetry Systems and Devices

3.3 Emphasize EMC/EMI education and awareness; management of potential sources of Electromagnetic Disturbance (EMD); establishment of mechanisms fro mitigation of EMI, management of facility equipment for EMC and tracking of EMI occurrences. At the same time, it strives to achieve a balance between the need for necessary radio communications (to include all wireless communication devices) and prevention of EMI.

4. Definitions.

4.1 Electromagnetic Compatibility (EMC) – The ability of an equipment and/or system to function satisfactorily in its electromagnetic environment without introducing intolerable EMD to anything in that environment.

4.2 Electromagnetic Disturbance (EMD) – Any electromagnetic phenomenon which may degrade the performance of an equipment and/or system.

4.3 Electromagnetic Interference (EMI) – Degradation in the performance of a piece of equipment, transmission channel, or system caused by EMD.

4.4 Far Field – A distance from the antenna of an RF transmitter that is more than several wavelengths of the transmit frequency.

4.5 Immunity – The ability of an equipment and/or system to perform without degradation in the presence of EMD.

4.6 Near Field – A distance from the antenna of an RF transmitter that is less than several wavelengths of the transmit frequency.

4.7 Portable Transmitters – Any device emitting Radio Frequency (RF) to include Wireless Local Area Networks (WLAN), two-way radios, two-way pagers, Blackberries, Cellular and PCS telephones, etc.

4.7 Radio Frequency – A frequency in the portion of the electromagnetic spectrum that is between the audio-frequency range and the infrared range. Note: The present practical limits of radio frequency are roughly 9 kHz to 3000 GHz.

4.8 Susceptibility – The vulnerability of an equipment and/or system to suffer performance degradation in the presence of EMD.

4.9 WLAN – Wireless Local Area Network

4.10 WMTS – Wireless Medical Telemetry Service

5. Responsibilities.

5.1 MTF Responsibilities

5.1.1 Commander – Will establish and maintain a written program to ensure compliance with EMC and this Guidance Document. Appoints an EMC Coordinator to facilitate the program for the facility. (Typically, the senior BMET or Clinical Engineer)

5.1.2 Biomedical Equipment Repair – Investigates medical device (equipment) problems in accordance with pertinent directives. Works with the EOC Committee, Medical Logistics, and Safety Officer on equipment/device-related problems. Submits FDA Form 3500A using ECRI's Computerized Product Reporting System (CPRS) for suspected EMI issues. Ensures new equipment purchases are in compliance with IEC 60601-1-2.

5.1.3 Environment of Care Committee (EOCC) – Provides oversight and review of all incidents involving medical devices. Determines if an incident needs to be sent to the manufacturer and/or FDA. Arranges Ad Hoc testing if needed.

5.1.4 Medical personnel (physicians, nurses, medical technicians, technologists) – When they become aware of information that reasonably suggests an EMI/EMC event occurred, reports that information to Medical Maintenance who will then report to the EOCC per established procedures.

5.2 AFMSA Clinical Engineering Branch (AFMSA/SGSLE)

5.2.1 AFMSA/SGSLE will monitor the EMC program through the use of the monthly data feeds from the MTFs and ECRI.

5.2.2 AFMSA/SGSLE will modify this guidance as needed.

6. Elements of an effective EMC program.

6.1 Training – Will be an initial and annually recurring requirement for all staff members.

6.1.1 Education should encompass the nature of EMI and how staff and patients can recognize and help prevent it.

6.1.2 Repair personnel should be trained in proper equipment servicing to ensure that EMC integrity is maintained.

6.1.3 Vendors, emergency services and other services who regularly enter clinical areas (e.g. security forces personnel) and are likely to use wireless communication equipment should be advised of the institution's EMC policies and procedures governing the use of RF devices.

6.2 Identification – Medical Maintenance/Clinical Engineering, through the EOC Committee, assumes the responsibility for seeing that the steps listed below are carried out, and reviewed as needed, to identify potential sources of EMI.

6.2.1 Equipment – The clinical/biomedical engineering staff should identify the RF sources most likely to influence electronic medical devices within the health care facility. A list of RF sources in each of the following categories should be established and updated as new communications equipment is brought into service.

6.2.1.1 On-site portable and mobile RF sources (e.g. hand-held transceivers, cellular and PCS telephones, pharmaceutical robots, RF ID tags, WLAN devices and medical telemetry receivers).

6.2.1.2 On-site fixed RF sources (e.g. rooftop paging transmitters, repeaters for land mobile communications, cellular and PCS base stations, WLAN Access Points, and telemetry transmitters).

6.2.1.3 Outside portable and mobile RF sources likely to be in the vicinity (e.g. two-way radios in ambulances, police and fire vehicles, taxis, shuttle buses).

6.2.1.4 Outside fixed RF sources (e.g. pager transmitters, cellular and PCS base stations, radio and television broadcast transmitters).

6.3 EMC Management – Mitigation of medical device EMI shall be achieved by management of RF sources and management of the EMC of all electrically-powered equipment used in the facility.

6.3.1 Hospitals will have clear, distinguishable signs specifying where patients and staff are permitted to use EMI devices - Portable Transmitters, Cellular or PCS telephones, etc.

6.3.2 In order to minimize the risk of EMI in and around areas of the facility where critical medical devices are used, including the ER, OR, ICU, CCU, Clinical Laboratory, Diagnostic Imaging, etc., the following precautions will be observed:

6.3.2.1 Portable transmitters such as two-way radios must be used only to receive (listen only).

6.3.2.2 Cellular and PCS telephones must be switched off.

6.3.2.3 Other forms of communication, such as house and pay phones should be available in these areas.

6.3.2.4 WLAN devices can be used once approved CON/CTOs are in place and spectrum analysis has been performed. Devices used with the WLAN, to include wireless access points, must never be placed within a three foot perimeter of any operating medical device. If EMI is suspected, the WLAN, being an unlicensed device, will be the first system turned off until the EMI problem has been resolved.

6.3.3 Portable transmitters, Cellular and PCS telephones are authorized for use in other areas of the hospital with the following precautions.

6.3.3.1 Two-way radios must be used only to receive or "listen only". Staff should be reminded that the EMI threat posed by two-way radios, in "talk" mode, extends 25 feet in all directions, including the floors above and below where the radios are being used.

6.3.3.2 At no time shall Cellular or PCS telephones, Blackberries, or Two-Way Pagers, be used within a three-foot perimeter of any operating medical device.

6.3.3.3 WLAN Access Points and/or WLAN devices shall not be placed or used within a three-foot perimeter of any operating medical device.

6.3.4 Fixed RF transmitters found to disrupt the performance of electronic medical devices within the facility should be removed, if possible. If it is impossible or impractical to relocate, alter, or remove those RF sources that cause medical device performance degradation, some form of protective EMI shielding should be considered. If RF shielding is installed, RF propagation patterns are affected both inside and outside the shielded area. Unless RF-Absorbing material is used, portable transmitters may need to be used with caution in or prohibited from the shielded areas. Any plans for protective EMI shielding must be cleared with the EMI Overwatch Committee and a Spectrum Analysis should be performed.

6.3.5 Before purchase, or leasing, all electrically-powered equipment (e.g. medical, communications, building systems, and information technology) ordered for use in the facility must be approved and coordinated through the EOCC to ensure that the equipment conforms to EMC standards and is compatible with the electrically-powered medical devices in the intended areas of installation or use.

6.3.5.1 Perform a site survey of the facility; depending on the size and complexity of the MTF or project, an outsourced survey agency may be required. The survey should include a comprehensive study of all devices operating in the radio frequency spectrum in the facility. Develop a frequency-management plan based on the spectrum survey to avoid interference from or with medical devices or other onsite wireless equipment.

6.3.5.2 In order to minimize the EMI risk, the EOCC must be given the authority to restrict equipment purchases. Equipment purchased will conform to present EMC standards. For medical electrical equipment, IEC 60601-1-2 specifies a general immunity test level of 3 V/m. Product-specific EMC standards may contain more stringent or more lenient requirements. Because of the uncertainties involved in EMC measurements, the variation in medical devices, and allowances in IEC 60601-1-2, medical devices that meet these standards can have a higher or lower immunity. IEC 60601-1-2 also allows wide latitude in the performance of the medical device, during the test, which can be claimed to meet the requirements of the standard. Therefore, the biomedical equipment service and repair manager/supervisor should examine the EMC test report to determine the claimed immunity of the device, the acceptability of the pass/fail criteria used and how the medical device performed during the test.

6.3.5.3 To reduce the risk of medical device EMI, RF transmitters purchased for use in the facility should have the lowest possible power rating that can be used to accomplish the intended purpose. For example, the facility should consider providing low-power (e.g. less than 100mW) cellular or PCS telephones instead of hand-held transceivers (e.g. 5W walkie-talkies) or higher power (e.g. 600mW or greater) cellular or PCS telephones for health care employees who need wireless communication.

6.3.6 The EOCC will be consulted prior to the installation and servicing of all electrically-powered medical and nonmedical equipment, communication systems, computers, LANs, and other intentional or unintentional sources of RF emissions that may be located near electronic medical devices.

6.3.7 On-site ad hoc radiated RF immunity testing (performed according to the present version of ANSI C63.18) should be considered when EMI is suspected, when RF transmitters are likely to operate in proximity to critical-care medical devices, in pre-purchase evaluation of new types of RF transmitters to determine their effect on existing medical devices, in pre-purchases evaluation of new electronic medical devices and when checking for age-related changes in medical device RF immunity. Ad hoc testing can be used to estimate the minimum distance that should be maintained between a specific RF transmitter and a specific medical device to mitigate EMI. The results of any ad hoc radiated RF immunity testing should be taken into account during revision of these policies and procedures.

6.3.8 EMC must be considered in the location of health care facilities and in site selection, design, construction, and layout of new facilities.

6.3.9 All equipment users and service personnel must follow the manufacturer's recommendations, as outlined in the appropriate literature, to avoid degrading the EMC characteristics of the devices they use and maintain.

6.3.9.1 Personnel servicing the equipment (BMETs and/or contractors) must ensure that shielding and other EMC components are not defeated, compromised, or omitted during servicing.

6.3.9.2 Manufacturer-specified replacement parts, to include transducers, cables, cover plates, screws and hardware must be used. Shortcuts such as leaving off cover plates, mounting screws or shielding to allow rapid re-entry to a device's internal components should be avoided. Service personnel must understand that the use of accessories, transducers, and cables other than those specified by the manufacturer may result in increased emissions or decreased immunity of the equipment.

6.4 Reporting and Tracking – All suspected incidents of medical device EMI must be reported to the medical maintenance activity.

6.4.1 Medical maintenance should assure that all EMI incidents are reported to the equipment manufacturer and to regulatory authorities. (Refer to the organization's Facility Incident Reporting Policy, AFI 41-201, etc.)

6.4.2 Medical maintenance will investigate incidents, make recommendations and report findings to the EOC Committee.

6.4.3 Medical maintenance will establish a methodology to track "No Defect" action codes by the location, date and time of the reported malfunction, if practical, to determine whether EMI may have been involved. Medical maintenance will report incidents of "No Defect" to the EOC Committee.

7. References

7.1 AAMI TR18:1997 – Guidance on Electromagnetic Compatibility of medical devices for clinical/biomedical engineers

7.2 AFMLL articles 06-1997 and 12-2000

7.3 ANSI C63.18-1997 – American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

7.4 ECRI

7.4.1 Health Devices; March 2003, July 2001 and November 2001

7.4.2 CHEM; April 2000

7.5 FDA Cell Phone Facts

7.6 IEC 60601-1-2 (September 2001)

7.7 IEEE Wireless LAN Edition; 2004

7.8 MIL-STD 461E; Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment.